

## **II. REMARKS**

Claims 2-11 and 14-16 are pending. Claims 14 and 16 are amended. No new matter is added.

### **I. The Examiner Interview**

Applicants greatly appreciate the courtesy extended to Applicants' representatives during the interview with the Examiners on February 18, 2009, wherein the difference in structure and function of the claimed monoclonal antibodies and the claimed hybridoma cells from the antibodies and cells in the cited art was discussed. The substance of the interview is incorporated herein.

### **II. The Rejections Under 35 U.S.C. § 102**

The Final Office Action and Advisory Action maintain the rejection of claims 2-5, 8, 9, 11 and 14-16 under 35 U.S.C. § 102 as allegedly being anticipated by Walker et al. 1994, Pirttila et al. 1994, WO0162801, or Naslund et al. 1994. The Final Office Action and Advisory Action also maintain the rejection of claims 2, 5, 8 and 14-16 under 35 U.S.C. § 102 as allegedly being anticipated by Solomon et al. 1996 or Huse et al. 2002.

As discussed during the February 18, 2009 interview, the Table submitted with the Amendment filed on January 14, 2009 demonstrates that none of the cited references disclose a monoclonal antibody having (1) an epitope encompassing A $\beta$ 11-15/17, (2) a reactivity to A $\beta$ 11-x, and (3) no cross-reactivity to A $\beta$ 1-40, as claimed.

Reconsideration and withdrawal of the rejections under U.S.C. § 102 are respectfully requested.

### **III. The Rejection Under 35 U.S.C. § 103**

The Final Office Action and the Advisory Action maintain the rejection of claims 2-5, 8, 9, 11 and 14-16 under 35 U.S.C. § 103 as allegedly being obvious over Huse et al. 2002 in view of Walker et al. 1994 and WO0162801.

As discussed during the February 18, 2009 interview, the Table submitted with the Amendment filed on January 14, 2009 demonstrates that none of the cited references disclose a monoclonal antibody having (1) an epitope encompassing A $\beta$ 11-15/17, (2) a reactivity to A $\beta$ 11-x, and (3) no cross-reactivity to A $\beta$ 1-40, as claimed.

Reconsideration and withdrawal of the rejection under U.S.C. § 103 are respectfully requested.

**IV. The Rejection Under 35 U.S.C. § 112, 1<sup>st</sup>**

The Final Office Action and the Advisory Action maintain the rejection of claims 14 and 16 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. In particular, the Advisory Action asserts:

[T]he specification, while being enabling for detection of Abeta11-40 in the CSF and brain section of Alzheimer's disease by using antibodies raised against Abeta peptides consisting of 6-8 amino acids of Abeta\_11 (6AA) or Abeta\_ (8AA) (SEQ ID Nos: 1-4), does not reasonably provide enablement for using the antibodies that specifically bind to Abeta11-x peptides to diagnose all amyloid-related diseases as broadly claimed.

In response, as discussed during the interview, amyloid deposits and plaques are the prominent pathological features of Alzheimer's disease and Down's syndrome. Although amyloid plaques may be detected in normal aging brains, they are present in smaller amounts and in a more restricted anatomical distribution. See the published specification at, e.g., paragraphs [0004]-[0006]. This is also supported by Naslund et al., Relative abundance of Alzheimer A $\beta$  amyloid peptide variants in Alzheimer disease and normal aging, Proc. Natl. Acad. Sci. USA, 91:8378-8382 (1994), and Iwatsubo et al., Full-length amyloid- $\beta$ (1-42(43)) and amino-terminally modified and truncated  $\beta$ 42(43) deposit in diffuse plaques, J. Pathology, 6:1823-1830 (1996), both submitted herein. Briefly, Naslund et al. discloses that Alzheimer brains contain several-fold more A $\beta$  variants, mainly A $\beta$ 1-40/42 and A $\beta$ 11-42, than normally aged brains. See page 8380, Discussion, first paragraph and page 8381, Table 1. Further, Iwatsubo et al. discloses that amyloid deposits comprising A $\beta$ 11-x are detected in specific areas outside of the cerebral cortex, such as the cerebellum, striatum and hypothalamus in brains of Alzheimer's disease and Down's syndrome but not in non-demented brains. See page

1825, Table 1 and Discussion starting at page 1827. Therefore, an observed accumulation of amyloid plaques containing AB11-x could be employed in a method for diagnosis Alzheimer's disease and Down's syndrome.

Reconsideration and withdrawal of the rejection of claims 14 and 16 under U.S.C. § 112, first paragraph, are respectfully requested.

**V. The Rejection Under 35 U.S.C. § 112, 2<sup>nd</sup> ¶**

The Final Office Action and the Advisory Action maintain the rejection of claim 16 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for use of the term "support".

As discussed during the interview, the term "support" is clearly defined in the specification. See paragraph [0065] of the published specification.

Reconsideration and withdrawal of the rejection of claim 16 under U.S.C. § 112, second paragraph, are respectfully requested.

**VI. The Rejection Under 35 U.S.C. §§ 102/103**

The Final Office Action and the Advisory Action maintain the rejection of claims 2, 6, 7, 15 and 16 under 35 U.S.C. §§ 102/103 as allegedly being anticipated by or obvious over U.S. Patent No. 6,984,720 ("the '720 patent").

In response, Applicants submit a declaration showing that the hybridoma cell line designated 5C in the '720 patent, which produces antibodies specific to human T cell surface molecule CTLA-4, is different from the hybridoma cell line J&JPRD/hAb11/2 (designated 5C in the present application), which produces the claimed monoclonal antibodies specific to AB11-x peptide.

Reconsideration and withdrawal of the rejection of claims 2, 6, 7, 15 and 16 under 35 U.S.C. §§ 102/103 are respectfully requested.

**VII. The Rejection Under 35 U.S.C. § 103**

The Final Office Action and the Advisory Action maintain the rejection of claims 2-11 and 14-16 under 35 U.S.C. § 103 over Huse et al. 2002 in veiw of Walker et al. 1994, WO1602801 and further in veiw of U.S. Patent No. 6,984,720.

As discussed during the February 18, 2009 interview, the Table submittied with the Amendment filed on January 14, 2009 demonstrates that none of the cited references disclose a monoclonal antibody having (1) an epitope encompassing A $\beta$ 11-15/17, (2) a reactivity to A $\beta$ 11-x, and (3) no cross-reactivity to A $\beta$ 1-40, as claimed.

Reconsideration and withdrawal of the rejection of claims 2-11 and 14-16 under 35 U.S.C. § 103 are respectfully requested.

**VIII. Conclusion**

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

/Laura A. Donnelly/

By: \_\_\_\_\_  
Laura A. Donnelly  
Registration No. 38,435

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
Phone: 732-524-1729  
Date: March 11, 2009

LD/YD

Attachments:

Naslund et al. (1994).  
Iwatsubo et al. (1996).  
Declaration